

REMARKSClaim Status/Support For Amendments

No new matter has been added by the amendments to the specification.

Page 6 of the instant disclosure was amended to correct a typographical error.

The Brief Description of the Figures was amended to add sequence identifiers for the sequences disclosed in the figures and to correct typographical errors.

A protocol in the experimental section of the detailed description has been amended to properly identify the trademark SEPHAROSE using capitalization.

The abstract has been amended to remove the legal phraseology ("said").

Claim 1 has been amended. Claims 2-35 have been canceled. Claims 36-43 have been added. Claims 1 and 36-43 are pending in the instant application.

No new matter has been added by the addition of new claims 36-43. The subject matter of new claims 36-43 corresponds to the subject matter of canceled claims 3-28. The above additions to the claims also find basis in the original disclosure at page 12, lines 2-12; page 17, lines 7-14; page 18, lines 5-7 and page 27, lines 17-23. The method of claims 36-40 is described in detail at pages 20-27. Page 28, line 9 to page 29, line 5 refers to the use of

various types of samples and their measurement. Figure 1 shows data derived when using the claimed method on samples obtained from a human patient. Page 28, line 1 to page 33, line 2 describes kits and their contents contemplated for use with the claimed methods. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

Sequence Compliance

Applicants have reviewed the entire specification including the figures and the claims for sequence disclosures. The only sequence found to be disclosed is the amino acid sequence identified as SEQ ID NO:1. Applicants provided a Sequence Listing (in both paper and computer readable form) disclosing SEQ ID NO:1 on April 19, 2002. However, Applicants noted that the first amino acid residue of SEQ ID NO:1 (D, as disclosed by the sequence shown in the figures) was not included in the originally filed Sequence Listing. Applicants herein provide a diskette containing a substitute Sequence Listing in electronic computer readable form to replace the previously submitted copy (filed on April 19, 2002). The diskette submitted herewith contains a Sequence Listing which adds the first amino acid residue (shown in the figures) to SEQ ID NO:1. As shown in Figure 1, the marker identified in patient sera

consists of amino acid residues 2-14 of SEQ ID NO:1. When carrying out mass spectrometric procedures, it is possible to fragment a whole molecule, depending upon the enzyme used for digestion. A sequence is often predicted from these fragments but often the sequence is not identified completely. It is conventional in the art to show the missing portions of the predicted sequence in parentheses. The first (D) amino acid residue of SEQ ID NO:1 is a predicted residue as indicated by the parentheses in Figure 1. The peptide sequence without the predicted first amino acid residue was shown in the original specification at page 27, line 18 and is shown in the figures with the first predicted amino acid residue. Thus, no new matter is added, the substitute Sequence Listing is for the purpose of clarifying the use of parentheses only. Applicants also herein provide a substitute paper copy of the Sequence Listing as contained on the diskette filed herewith. The computer readable form of the substitute Sequence Listing is identical to the paper copy of the substitute Sequence Listing. The amendments to the claims and specification limiting the marker sequences to specific amino acid residues are also made for the purpose of clarification of the use of parentheses only. The claims as herein amended limit the marker sequence to amino acid residues 2-14 of SEQ ID NO:1.

Restriction/Election

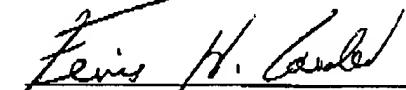
In a telephone conference on August 12, 2003, the Examiner indicated that a Restriction requirement would be necessary in the instant application. Applicants requested the entry of a Preliminary Amendment prior to the Restriction requirement. Applicants would elect the marker claim (claim 1) for examination on the merits when/if restriction is required. However, Applicants respectfully request that the Examiner consider re-joining the claims after the marker claim is found allowable.

The instant application is related in claim format to several pending applications of which serial number 09/846,352 is exemplary. The biopolymer marker of serial number 09/846,352 was found to be novel and subsequently claims reading on methods and kits limited to its use were rejoined with the claims reading on the biopolymer marker under *Ochai*. Similarly, if the peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 of the instant application is found to be novel, methods and kits limited to its use should also be novel. Thus, in an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner enter the new claims (36-43) added herein by amendment and consider rejoining them with claims reading on the biopolymer marker consisting of amino acid residues 2-14 of SEQ ID NO:1 when such claims to the biopolymer marker are found allowable.

CONCLUSION

Applicants now respectfully request an examination on the merits in the above-referenced application.

Respectfully submitted,



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